

NATIONAL VAPERS CLUB



Research Educate Protect

Meeting with the White House Office on Information and Regulatory Affairs (OIRA) and Office of Management and Budget (OMB) (RIN#0910-AG38)

December 7, 2015

Cheryl Richter, Philip Roseman and Chris Imlah
National Vapers Club Board of Directors

12/7/2015



When we were kids, everyone smoked.
 Ironically, the same year I was born, the first electronic
 cigarette was patented – but never brought to market.

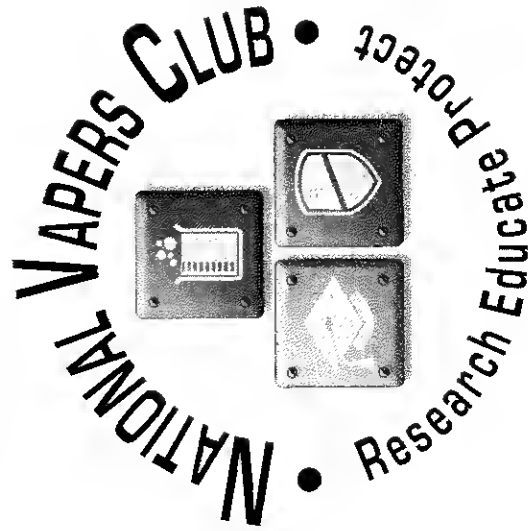


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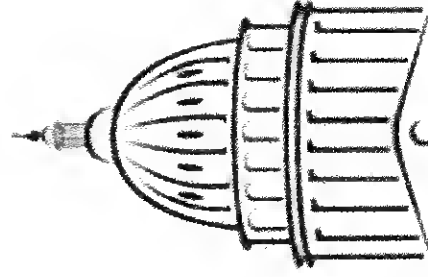
Cheryl L. Richter



Co-Owner



Secretary/Treasurer



SEAT

Co-Chair NY Chapter

Vaping Industry:

Ex-Smoking Entrepreneurs – NOT Big Tobacco

- 2007 – only “ciga-likes” on the market
- Victims of tobacco became vapers
- Vapers became hobbyists. Made “modifications”:
 - Added safety features (temperature control, safety shut offs, short circuit protection)
 - Longer lasting
 - More appealing
 - Highly effective
 - Safety protocols in e-liquid manufacturing
- Hobbyists became entrepreneurs—owners of:
 - Manufacturing plants, e-liquid labs, vape shops, distribution centers
- Entrepreneurs are a unified community with Anti-Big Tobacco sentiment
- Consumers and industry passionate in mission to help smokers

Vaping Products are for Adult Smokers



“Regular use of electronic cigarettes amongst children and young people is rare and is confined almost entirely to those who currently or have previously smoked.”¹

1. Action on Smoking and Health, April 2014

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We Don't Market to Children



MUST BE 18 OR OLDER
TO ENTER AND SHOW
A VALID ID.
FAKE IDs WILL BE
CONFISCATED AND
THE POLICE WILL BE
CALLED

(because Big T marketed to Us)



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Our mission is to get the older, hard-core generation OFF cigarettes.

According to
SmokingAnswers.com:

“One of the harmful effects of smoking is the damage it does to your palate. Smoking deadens your taste buds and reduces the tastes you experience. Once you quit smoking, that steak is going to be juicier, that apple tastier and that candy bar a little sweeter.”

Once a vaper gets used to nicotine delivered via flavors, they react negatively to the stench of cigarettes. Flavors help keep them from smoking.

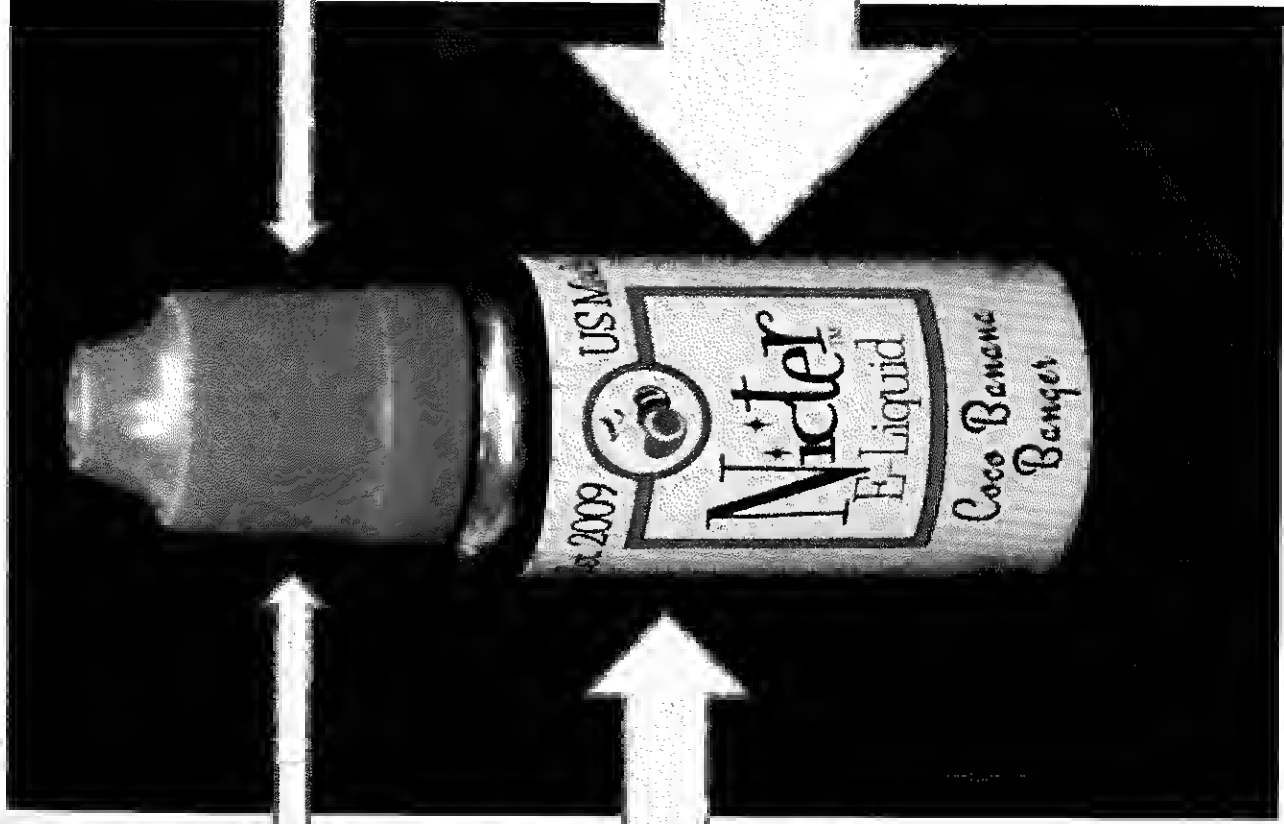
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**Al Bender, 68, inspiration for
“Al’s Cookie” Nicter Flavor
based on an actual cookie
recipe he liked**



**Child-
Proof
Cap**

**Tamper
Proof
Seal**



Shake Well.
0mg (0.0% Nic)
Exp: 01/16 L718B
cherryvape.com

Left side of bottle:

- Nic Level
- % of Nic per volume weight
- Expiration date
- Lot number

Right side of bottle:

Ingredients:

USP- Propylene Glycol*,
USP-Vegetable Glycerin*,
USP-Nicotine,
USDA-Food Flavoring*.

Warning: Keep out of
reach of children & pets.
This product may contain
nicotine which is addictive.
Avoid contact with eyes If
swallowed, contact Poison
Control: 800-222-1222

Kids love their parents
more than flavors.



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Dr. Michael Siegel,

Professor in the Department of Community Health Sciences, Boston University School of Public Health

“These deeming regulations should really be called ‘The Cigarette Protection Act of 2015.’

They create stringent requirements for electronic cigarettes, while allowing the much more toxic real cigarettes to remain on the market, unencumbered and unchallenged by competing products that are much safer and that could have otherwise transformed the nicotine market away from combustible tobacco products, thus saving thousands of lives.

The regulations will decimate the e-cigarette industry, forcing thousands of small vapor shops and e-cigarette sellers out of business. This will no doubt result in many vapers returning to cigarette smokers and many potential quitters from trying to quit using these products.”

Dr. Carl Phillips

Tobacco Harm Reduction Researcher/ Scientific Director of CASAA

"Any normal use of the word [regulation] in the context of products refers to rules for product characteristics, performance standards, manufacturing standards, labeling, and the like, such that a product in the category must meet the rules to be allowed on the market.

FDA's tobacco "regulation" includes almost none of that...

And there may never be, because **the real effect of FDA "regulation" is simply to make it nearly impossible for manufacturers to introduce a new product or even make changes to existing products."**

My Company's Cost of PMA

(E-Liquid Only)

70 Flavors + 6 Nicotine Levels = 420 SKU's

Pre-Market Application Costs

(estimated by experts at between \$1M - \$20 each)

@ \$1million each = \$420,000,000.00

@ \$10 million each = \$4,200,000,000.00

@ \$20 million each = \$8,400,000,000.00

2014 Total Company Gross Revenue = \$560,093.00

Who Could Possibly Afford PMA?

- Philip Morris USA (Altria)
- R.J. Reynolds
- Lorillard

If they decide to apply would their applications even be accepted?

The Endgame is In Sight, So Let's Run Towards It, Not Away from It

"Anyone who would ponder the endgame must acknowledge that the continuum of risk exists and pursue strategies that are designed to drive consumers from the most deadly and dangerous to the least harmful forms of nicotine delivery. "

Mitch Zeller, Reflections on the 'endgame' for tobacco control, Sept 2012

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According to the CDC

- 3.7% of US adults currently use e-cigarettes
- Among current cigarette smokers who had tried to quit smoking in the past year, more than one-half had ever tried an e-cigarette
- 20.3% who had tried to quit in the past year were current e-cigarette users
- Nearly one in four recent former cigarette smokers (22.0%) currently used e-cigarettes

-CDC/NCHS, October 2015

Consumers Value their Vaping Products

Spending Habits of Vapers:¹

- 95.7% use vaping products exclusively
- 36.2% typically spend \$20-\$50 a month on vapor products
- 37.9% typically spend \$50-100 a month on
- 19.8% spend over \$100
 - Budget on flavors:
 - 54.6% all/almost all
 - 36.5% half or more than half flavors

With No Legitimate Way to Get the Vaping Products they Want , What Will Consumers Do?

- Dangerous Consequences of no commercially available, regulated flavors or electronic products:
 - 29.3% would go back to smoking¹
 - 66.1% would mix their own e-liquid¹
- Vibrant Black Market:
 - China poised to take over with no need to comply to US regulations
 - Sub-standard mixing by non-experts = huge problem for public health. Ingredients are readily available at supermarkets/pharmacies and free-base (100%) nicotine easily ordered from China
 - Wire, battery & flashlight modified into electronic cigarettes by non-technical experts
 - No electronic safety (short circuit protection, auto-shut off, temperature control)
 - No way to track or police

Widely Available Vaping Products Appropriate for the Protection of Public Health

The FDA should only require vapor product and e-liquid manufacturers to prove that their products meet safety and product standards in order to demonstrate that they are “appropriate for the protection of the public health”:

1. Because of the importance of vaping products as a valuable tool for harm reduction for smokers
2. Because of the almost certain dangers that would be caused by a Black/DIY market
3. Because it will lead vapers and those who are trying to use them to quit back to smoking
4. Because e-cigarettes are poised to save Medicaid billions of dollars, according to State Budget Solutions Policy Analysis (Addendum)

With No Way to Sell Product, What Will the Vaping Industry Do?

- Hundreds of manufacturing facilities shut down
- 15,000+ vape shops close
- 100,000+ people unemployed
- State and Federal tax revenue eliminated
- Business debt unpaid
- Houses foreclosed
- Childrens' College tuition unpaid
- Futures destroyed

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FDA's Current Deeming Regulations

would ensure:

- Smokers keep smoking
- The smoking rate will increase
- Vapers turn to black/DIY market with no safety standards (causing injuries, poisonings and illness)
- Vaping industry will shut down
- Big Tobacco will get bigger
- People will keep dying from smoking related illnesses
- 9 million vapers, their children, families, friends and doctors will truly believe that our Big government cares more for Big Tobacco and Big Pharma than citizens' lives

We Believe:

- FDA violates multiple sections of Executive Order 12866, giving OIRA ability to rework FDA's Deeming Regulations for a more sensible approach. (see addendum)
- Regulation should establish uniform manufacturing, safety, and quality control standards for vapor products
- Regulatory bodies can and should work with industry associations for appropriate standards